Remarks

Status of Claims

Claims 1-20 are pending. Claims 1-9 are directed to non-elected embodiments and have been withdrawn. Claims 10-20 stand rejected. Claims 21 and 22 are new.

Rejections

Rejections Under 35 U.S.C. § 103(a)

Claims 10-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application 2004/0186390 issued to Ross et al. (hereinafter referred to as "Ross") in view of U.S. Patent Number 4,294,262 issued to Williams et al. (hereinafter referred as "Williams"), further in view of U.S. Patent Application 2005/0094707 issued to Lee et al. (hereinafter referred to as "Lee"), and further in view of U.S. Patent Application 2002/0087057 issued to Lovejoy et al. (hereinafter referred to as "Lovejoy").

In particular, with respect to claims 10 and 14, the Examiner asserts that Ross discloses a mouthpiece apparatus for measuring a plurality of physiological signals. The Examiner asserts that the Ross apparatus comprises a mouthpiece positioned in line with a fluid channel consisting of ultrasonic transducers for measuring peak flow through the fluid channel (citing Figures 23 and 24 as described in paragraphs [0114] - [0121]; note that in paragraph [0009] and [0060] that the mouthpiece, fluid channel, and respiratory analyzer are considered one unitary structure), and memory for storing acquired physiological parameters (citing Figure 1F memory 80 as disclosed in paragraph [005 11 and [0152]). In addition, the Examiner asserts that Ross further discloses other suitable forms of determining respiratory flow including thermal methods, pilot tubes, and

turbines (citing paragraph [013 I]), but is silent on using magnetic impellors with a field-effect transistor counting the number of rotations per second of the impellor. Rather, the Examiner asserts that Williams is analogous art and discloses such a method of analyzing respiratory performance using a rotary turbine with attached magnets and wherein rotation is calculated relative to respiratory flow (citing Williams Figure 2 as described in column 1 lines 46-56 and column 3 lines 8-22). In brief conclusion, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the ultrasonic transducers of Ross with the magnetic rotary turbines as disclosed in Williams, because Williams discloses magnetic rotary turbines as improved turbine methods of detecting respiratory flow capable of isolating respiratory flow from mechanical noise of rotary mechanisms (citing Williams column 1 lines 32-42).

With respect to additional limitations in claims 10 and 14, the Examiner asserts that a modified Ross teaching discloses that additional physiological sensors can be attached within the mouthpiece to obtain other biological system conditions such as cardiac output using temperature and blood pH sensitivity (citing Ross paragraphs [0126] and [0176] - [0188]), but is silent on the types of sensors used as claimed by the Applicant to obtain these parameters. Rather, the Examiner asserts Lee as analogous art which discloses an electronic thermometer probe with a metallic tip used for placing in a subject's oral cavity to obtain temperature readings (citing Lee Figures 5A and 5B as disclosed in paragraphs [0018] and [0020] - [0022]; the probe as being capable of being placed in a subject's oral cavity would therefore be capable of being placed under the subject's tongue). In conclusion, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the means of obtaining temperature for cardiac output as disclosed in Ross with an electronic thermometer probe as

disclosed in Lee, because Lee teaches such electronic probes with metallic tips are faster, safer, and more efficient than conventional thermometer probes (citing Lee paragraph [0005]).

For yet another limitation in claim 10 and 14, the Examiner asserts another combination to arrive at the claimed invention. In particular, the Examiner asserts that a combination of a modified Ross in view of Williams and Lee teaches obtaining blood pH levels for determining cardiac output, but does not teach a secondary probe with a metallic tip disposed in the mouthpiece for measuring saliva acidity. Rather, the Examiner relies on Lovejoy, which he asserts is another analogous art reference, which discloses a probe for measuring pH levels in the mouth located underneath the user's tongue to noninvasively detect levels of perfusion failure related to blood flow (citing Lovejoy Figures 1 and 8 paragraphs [0008] and [0050]; [0036] indicates metal contacts). The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the cardiac output configuration disclosed in Ross with the pH probe as disclosed in Lovejoy, because Lovejoy discloses such a probe as being noninvasive (capable of determining pH levels from saliva as opposed from the blood) and still be capable of detecting blood perfusion failure that could indicate early signs of patient condition deterioration (citing Lovejoy paragraph [0008]).

In conclusion, the Examiner concedes that the applied references of Ross, Williams, Lee, and Lovejoy do not specifically disclose obtaining values of basal metabolic temperature and waking peak flow. However, the Examiner asserts that based on the Applicant's specification, in particular page 11 lines 19-24, basal metabolic temperature and waking peak flow are no different from standard values of temperature and peak flow other than when the device is used to obtain these values, and as such the specific types of temperature and peak flow claimed by the Applicant appears to be directed to intended use, specifically when to use the device. The

Examiner asserts a conclusion, that although not expressed, the apparatus of Ross would therefore be capable of obtaining such values by merely using the device at the appropriate time, in this case after a subject has just awoken.

The Applicant disagrees with the Examiner's assertion that the combination of Ross, Williams, Lee and Lovejoy arrive at the claimed invention. In the least, neither Ross, Williams, Lee, Lovejoy nor a combination teach or suggest, inter alia, a mouthpiece configured to be placed in a user's mouth and forming a fluid tight seal therewith during exhalation to direct exhaled fluid into the apparatus, with a rapid thermometer probe with a metallic tip and a second probed positioned in the mouthpiece and measuring basal metabolic temperature and saliva acidity together in the user's mouth.

In particular, the Examiner asserts that Ross teaches additional physiological sensors can be attached within the mouthpiece to obtain other biological system conditions such as cardiac output using temperature and blood pH sensitivity (citing Ross paragraphs [0126] and [0176] - [0188]), but is silent on the types of sensors used as claimed by the Applicant to obtain these parameters. In reviewing the cited paragraphs, the Applicant cannot find a suggestion or any motivation to position any sensors in the mouthpiece area, let alone two probes positioned in the mouthpiece to collect data. Rather, Ross teaches that in other embodiments, some or all of the functions of the computation module may be included within the flow module, and the flow module and computation module may be combined into a unitary device, while in other embodiments, certain components related to sensors and/or transducers may be located within the flow module, and other components located within the computation module. Ross even discloses that other configurations are possible, which include cardiac output determination, and use of activity monitors and physiological monitors. In exemplary embodiment supporting

cardiac output and metabolic rate monitoring, Ross teaches that monitoring by a health professional over time, and the data used to provide improved rehabilitation programs, wherein the physiological response to exercises of increased intensity can be used to provide feedback to the subject, for example by comparing the determined data with those of healthy and diseased individuals, or comparing the data with predetermined values (such as the boundaries of certain exercise regimes, maximum values, and the like). In the exemplary embodiments, wherein flow module or computation module monitoring is taught, Ross briefly describes that the apparatus may also receive signals from one or more physiological sensors, such as a pulse oximeter, heart rate monitor, EKG, and the like, so as to monitor the health of the subject. Nowhere does Ross teach or suggest positioning of these sensors in the mouthpiece. While Ross discloses that certain components related to sensors and/or transducers may be located within the flow module and other components located within the computation module, Ross does not discloses a blunt-ended instrument having a sensor positioned in the mouthpiece.

Furthermore, Ross generally teaches a respiratory analyzer comprising a flow module 10 having a respiratory connector 16 through which the subject breathes. The flow module 10 also has an atmospheric port 14 , so that inhaled gases pass through port 14 into the flow module, through a flow pathway enclosed by the housing of the flow module, and further passing through the respiratory connector 16 into the subject's mouth. The flow module comprises an oxygen sensor, covered by window 12 , and a flow meter (not shown). The harness includes holes for better ventilation, and may be formed from a transparent polymer. A support harness 18 supports the flow module so that the respiratory connector is in fluid communication with the subject's mouth. Straps 20 and 22 connect to the support harness 18 using connectors 28 a and 28 b, the straps passing around the subject's head. In general, a person can measure their metabolic rate

during exercise, through determination of consumed oxygen volume, carbon dioxide production, or some other method. There would be no reason to include one probe, let alone two probes, into the Ross mouthpiece as this would hinder the ability to perform exercise during monitoring; hence, destroying the intended function of the Ross apparatus.

That which Ross lacks is neither taught nor suggested in Williams, Lee or Lovejoy.

As pointed out by the Examiner, Williams is relied upon in showing a method of analyzing respiratory performance using a rotary turbine with attached magnets and wherein rotation is calculated relative to respiratory flow (Examiner cites Williams Figure 2 as described in column 1 lines 46-56 and column 3 lines 8-22). Clearly, Williams does not teach nor suggest positioning the probe in a mouth piece next to another second probe.

Lee generally discloses basic electrical thermometer 40 having a main body 41 equipped with a tapered probe portion 42,wherein the probe portion 42 and a metallic tip 43 mounted on its front end under a human being's armpit or into one's oral cavity or anus. In general, the main body 41 and the probe portion 42 are made from a heat insulating plastic material and are formed together in one single piece. The metallic tip 43 , which appears in the form of a shell with a blunt tip, is fabricated by stamping a metal sheet. The front end of the probe portion 42 is fitted into the opening of the metallic tip 43 . Furthermore, a display unit 44 is installed on the main body 41 for users to easily read measurement data, in a monolithic design. While Lee teaches a basic thermometer having a tapered probe piece, Lee does not teach positioning the probe in a mouth piece next to another second probe.

Likewise, Lovejoy generally teaches a method and apparatus for assessing tissue perfusion of a patient. The apparatus includes a probe for contacting the mucosa tissue in the upper respiratory/digestive tract of the patient, and a sensor coupled to the probe for directly

detecting a pH measurement of the mucosa tissue and for generating an electrical signal in response to the detected pH measurement. There is no teaching of positioning a probe in a mouth piece next to another second probe.

Since none of references cited, nor a combination, teach or suggest each and every limitation recited claims 10 and 14, then claims 10 and 14 cannot be found obvious in view of the cited combination. Additionally, those that depend from claims 10 and 14, namely claims 11-13 and 15-20, are patentably distinct from the combination for the same reasons. Reconsideration and allowance of claims 10-20 is therefore requested.

New claims

New claims 21 and 22 are submitted for examination. Claims 21 and 22 are believed to be patentable because the references of record do not teach nor suggest an apparatus having the combination of a mouthpiece with a rapid thermometer probe and a second probe extending in and through the mouthpiece positioned on each side of the tongue in the mouth. Consideration and allowance of these new claims is requested.

Conclusion

For all of the foregoing reasons, Applicant respectfully contends that the application is now in condition for allowance. Accordingly, Applicant respectfully requests entry of the new dependent claims 21 and 22, reconsideration and allowance of claims 10-20, and issuance of a Patent for the subject invention. If the Examiner cares to discuss anything presented here to further prosecution of this application, he is invited to contact the undersigned Attorney for the

Applicant. Please charge any additional requisite fees relating to this amendment and response to Deposit Account No. 501581.

Respectfully submitted,

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